

## **REMARKS/ARGUMENTS**

The Patent Office examines and rejects claims 1-16, 49-5, 62-79 and 81-86. Applicants amend claims 1, 12, 49, 54, 56 and 57. Applicants submit that no new matter is added therein as amendments to claim 12 are supported at least at paragraphs [0080] and [0087]; amendments to claims 1, 56-57 are supported at least at paragraphs [0004], [0006], [0007] and Figures 1A, 1B and 4; amendments to claims 49 and 54 are supported at least at paragraphs [0002], [0004], [0043], [0048] and [0055]-[0057] and [0074] and Figures 1A, 1B and 4; and additional claim 87 is supported at least at paragraphs [0002], [0004], [0006], [0007], [0043] and [0074] and 1A, 1B and 4 of the application.

Hence, Applicants respectfully request reconsideration of the pending claims and consideration of the additional claims in view of the remarks herein.

### **Double Patenting**

Applicants appreciate the Patent Office's provisional obviousness-type double patenting rejection of claims 1-16, 49-58, 62-79 and 81-84 provisionally rejected over claims 15-21, 24, 31-43 and 53-60 of co-pending U.S. Patent Application No. 10/664,308. Applicants will address the provisional double patenting on issuance of one of the involved patents.

### **Claims Rejected under U.S.C. §112**

Claims 12 is rejected under 35 U.S.C. §112, second paragraph for alleged unclear terms. Applicants disagree.

However, Applicants amend claim 12 and submit that, as amended, claim 12 is clear.

### **Claims Rejected Under 35 U.S.C. §103**

The Patent Office rejects claims 1-3, 5-7, 13-14, 16, 49-58, 62, 76-77, 82 and 84 under 35 U.S.C. §103(a) as being unpatentable over U.S. Publication No. 2002/0193685 to Mate et al. (Mate) in view of U.S. Publication No. 2002/0065461 to Cosman (Cosman). Claims 4 and 83 are rejected under 35 U.S.C. §103(a) as being unpatentable over Mate in view of Cosman as

applied to claim 1 above, and further in view of U.S. Patent Pub. No. 2003/0007601 to Jaffray et al. (Jaffray). Claims 8-9, 12, 78-79 and 81 are rejected under 35 U.S.C. §103(a) as being unpatentable over Mate in view of Cosman as applied to claims 6-7 above, and further in view of U.S. Patent No. 5,757,953 to Jang (Jang). Claims 10-11 are rejected under 35 U.S.C. §103(a) as unpatentable over Mate in view of Cosman and Jang as applied to claim 8 above and further in view of U.S. Patent No. 5,446,548 to Gerig et al. (Gerig). Claims 15, 63-72 and 74 are rejected under 35 U.S.C. §103(a) as being unpatentable over Mate in view of Cosman as applied to claims 1 and 14 above, and further in view of U.S. Patent No. 6,073,044 to Fitzpatrick et al. (Fitzpatrick). Claims 73 and 75 are rejected under 35 U.S.C. §103(a) as being unpatentable over Mate in view of Cosman and Fitzpatrick as applied to claim 64 above, and further in view of US Patent No. 5,622,187 to Carol ("Carol"). Claims 85-86 are rejected under 35 U.S.C. §103(a) as being unpatentable over Mate in view of Cosman as applied to claims 1 and 58 above, and further in view of U.S. Patent No. 6,398,710 to Ishikawa et al. ("Ishikawa"). For a claim to be obvious every limitation of that claim must be taught by at least one property combined reference.

Applicants respectfully disagree with the rejection above and submit that independent claim 1 is patentable over the cited references for at least the reason that none of the references teach imaging a plurality of markers in a first and in a second imaging modality, where the markers are implanted in a body; and determining first coordinates and second coordinates, wherein at least a plurality of said markers are implanted in soft tissue of the body, as required by claim 1.

Mate teaches a primary purpose of allowing target 12 to be accurately positioned at a treatment machine isocenter by acceptably aligning target and machine isocenters 40 and 22 for radiation delivery from source 18 to irradiate a target (see paragraphs 35 and 39). In Mate, the imaging is performed only by exciting markers 30 with excitation source 32 so that markers 30 resonate at a selected unique frequency and generate an underlying low energy radial-frequency magnetic signal measurable from outside body 14 by array 34 of sensors 36 (see paragraph [0036]). Thus, Mate does not teach imaging a plurality of markers in a first and in a second imaging modality, where the markers are implanted in a body; and determining first coordinates and second coordinates, wherein at least a plurality of said markers are implanted in soft tissue of

the body, as required by claim 1. Moreover, Mate fails to teach the planned treatment beam isocenter and treatment beam isocenter of claim 2; the first and second imaging modalities of claim 4; the false markers of claim 12; the gantries of claim 60; the different session of claim 61; or the limitations of additional claims 82-84.

Cosman teaches percutaneously fixing a stud section to the iliac crest bone of the pelvis during treatment, so that an array of marker spheres can be attached to the stud above the surface of the skin at the time of treatment (see paragraph [0061] and Figure 3C). The markers are geometric objects to indicate position of patient location that are visible to a camera (see paragraph [0063]). Thus, the primary purpose of Cosman is to have the markers external to the skin so that they can be imaged with a camera in order to provide an optical tracking system to compare the location of the markers in images picked up a camera system to align the target where target with the isocenter of a beam (see paragraphs [0064]-[0065] and Figure 3C). Thus, Cosman can not teach imaging a plurality of markers in a first and in a second imaging modality, where the markers are implanted in a body; and determining first coordinates and second coordinates, wherein at least a plurality of said markers are implanted in soft tissue of the body, as required by claim 1.

Applicants also disagree with the rejection above of independent claims 49 and 54 for at least the reason that the cited references do not teach imaging markers in a first and second imaging modality, where the markers are implanted in a body; and determining first coordinates and second coordinates, wherein the first imaging modality is an x-ray imaging modality, the first beam isocenter is an isocenter of an x-ray image system, the second imaging modality is an x-ray imaging modality, and the second beam isocenter is a high energy beam of radiation of a treatment machine, as required by amended claims 49 and 54.

Mate teaches a primary purpose of allowing target 12 to be accurately positioned at a treatment machine isocenter so that ionizing radiation is accurately delivered to target 12 (see paragraph [0035]). Mate teaches acceptably aligning target and machine isocenters 40 and 22 for radiation delivery from source 18 to irradiate a target (see cols. 35 and 39). In Mate, the imaging is performed in real time and during treatment (see paragraphs [0035], [0037] and [0039]). Mate also teaches that the imaging is performed only by exciting markers 30 with

excitation source 32 so that markers 30 resonate at a selected unique frequency and generate an underlying low energy radial-frequency magnetic signal measurable from outside body 14 by array 34 of sensors 36 (see paragraph [0036]). Thus, Mate does not teach imaging a plurality of markers in a first and in a second imaging modality, where the markers are implanted in a body; and determining first coordinates and second coordinates, wherein the first imaging modality is an x-ray imaging modality, the first beam isocenter is an isocenter of an x-ray image system, the second imaging modality is an x-ray imaging modality, and the second beam isocenter is a high energy beam of radiation of a treatment machine as required by claims 49 and 54.

Cosman teaches percutaneously fixing a stud section to the iliac crest bone of the pelvis during treatment, so that an array of marker spheres can be attached to the stud above the surface of the skin at the time of treatment (see paragraph [0061] and Figure 3C). The markers are geometric objects to indicate position of patient location that are visible to a camera (see paragraph [0063]). Thus, the primary purpose of Cosman is to have the markers external to the skin so that they can be imaged with a camera in order to provide an optical tracking system to compare the location of the markers in images picked up a camera system to align the target where target with the isocenter of a beam (see paragraphs [0064]-[0065] and Figure 3C).

Thus, the camera of Cosman images the markers relative to photons reflected from the markers, but does not teach determining first coordinates and second coordinates, wherein the first imaging modality is an x-ray imaging modality, the first beam isocenter is an isocenter of an x-ray image system, the second imaging modality is an x-ray imaging modality, and the second beam isocenter is a high energy beam of radiation of a treatment machine as required by claims 49 and 54.

In addition, by imaging markers that reside internal to a body in two modalities as required by the independent claims, some embodiments described in the specification, for example, without limitation thereto, may provide one or more of: (1) the benefit of measuring radiation received by internal markers near anatomical landmarks to extrapolate the amount of radiation delivered to anatomical landmarks to minimize damage to such areas from treatment (see paragraph [0043] of the Application; and claims 85-86); (2) the benefit of determining more accurate positions of soft tissue internal body areas having internal markers situated therein to

ensure that a target volume (e.g., tumor) receives sufficient radiation and that injury to the surrounding and adjacent soft tissue non-target volumes (e.g., healthy tissue) is minimized (see paragraphs [0055] and [0074] of the Application; and claims 1 and 56-57); (3) the benefit of imaging internal markers left in soft tissue of the body to provide more accurate positioning of a target volume during multiple treatment sessions to account for daily treatment machine setup variation and various types of soft tissue and/or organ movement (see paragraph [0078] of the Application; and claims 1 and 56-57); and/or (4) the benefit of imaging in an x-ray imaging modality, wherein the first beam isocenter is an isocenter of an x-ray image system, and imaging in a second x-ray imaging modality, and the second beam isocenter is a high energy beam of radiation of a treatment machine (see paragraphs [0043], [0048] and [0055]-[0057] and [0074] of the Application; and claims 49 and 54. Thus, the invention may have any one or any combination of the foregoing benefits. However, the references do not contemplate or enable such benefits.

In addition to being dependent upon allowable base claim 1, Applicants also disagree with the rejection of dependent claims 56 and 57 as amended for at least the reason that the cited references do not teach imaging markers in a first and second imaging modality, wherein the second beam isocenter is a high energy radiation treatment beam and the markers are injected or expelled into soft body tissue, as required by claims 56 and 57. As noted above, Cosman only teaches fixing the markers to bone.

Moreover, Cosman does not teach the planned treatment beam isocenter and treatment beam isocenter of claim 2; the non-marker objects of claim 12; the first modality occurs during a first treatment session, and the second imaging modality occurs during a different second treatment session of claim 58; an adjustment based on how fixed spacings are between imaged markers implanted in a target over the course of treatment of claim 63; a rigid target of claim 73; a deformable target of claim 74; a first modality on a treatment planning machine and a second modality on a treatment machine as required by claims 82 and 84; a first modality of CT imaging kilovolt imaging, and megavolt imaging of claim 83; or measuring radiation received by the markers of additional claims 85-86. As noted above, camera system C of Cosman cannot scan markers implanted in a body (see paragraphs [0034] and [0035] and FIGs. 1-2). Hence, Cosman does not teach the above noted limitations of claims 2, 12, 58, 63, 73-74, or 82-86.

In addition to being dependent upon allowable base claim 1, Applicants disagree with the rejection above of claims 85-86 for at least the reason that the cited references do not teach measuring radiation received by the markers having coordinates determined relative to a first and second beam isocenter, as required by claims 85 and 86. As noted by the Patent Office, neither Mate nor Cosman teaches such limitations. Moreover, Ishikawa only teaches imaging markers using radio frequency transmission signals received by receivers 126 and 128 (see col. 4, lines 25-50, claim 4 and Figure 2), but does not teach the above-noted limitations.

Any dependent claims not mentioned above are patentable over the cited references for at least the reasons provided above of their base claims as well as for additional limitations of dependent claims.

Hence, Applicants respectfully request withdrawal of all the rejections above for all of the claims.

#### Additional Claims 87

Applicants submitted additional claim 87 is patentable over the cited references for at least the reasons provided above of its base claim as well as for additional limitations of dependent claim 87 (e.g., such as is noted above for claim 1 plus claim 49).

CONCLUSION


In view of the foregoing, it is believed that all claims now pending patentably define the subject invention over the prior art of record and are in condition for allowance and such action is earnestly solicited at the earliest possible date.

If necessary, the Commissioner is hereby authorized in this, concurrent and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2666 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17, particularly extension of time fees.

Respectfully submitted,

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Dated: May 4, 2009

  
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CERTIFICATE OF TRANSMISSION

I hereby certify that this correspondence is being submitted electronically via EFS Web on the date shown below to the United States Patent and Trademark Office.

  
Suzanne Johnston

5/4/09  
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